

Remarks

The claim set above corrects the typographical error by which claim 85 was listed twice with two different statuses.

Double Patenting

The double patenting rejection over U.S. 6,124,620 has been withdrawn. However, some confusion exists over the rejection and the argument previously made. Applicants argument related to a different patent, U.S. 6,214,620 to Johns and Marban.

The reasons for withdrawal states that the cited patent was to “another person with the surname Abraham.” But the cited patent U.S. 6,124,620 is to two individuals (Gardner; Mark I., Gilmer; Mark C.), neither of which is named Abraham.

Please clarify the basis of the double patenting rejection and the reason for withdrawal.

The rejection of claims 86, 94, 98, and 99 under 35 U.S.C. § 112, first paragraph

Claims 86, 94, 98, and 99 stand rejected as allegedly comprising new matter.

New dependent claim 99 is allegedly not fully supported because it is generic (“decreases the ADP80”) and is supported solely by a specific disclosure of a specific experiment in which the ADP80 was decreased 20 %.

Solely in order to advance prosecution, claim 99 is cancelled. Applicants do not agree that merely because a particular example of a decrease was given other amounts of decrease are not supported.

Similarly, new claim 98 is drawn to an increase in conduction velocity of fibroblasts, but this too is allegedly supported solely by an example disclosing a particular experiment. To advance prosecution, this claim too is cancelled, without agreeing with its premise.

However, the rejection of the other claims (claims 86 and 94) for the same reason is incorrect. The mere fact that a generic method is not supported by a disclosure of every possible species or embodiment does not make the support insufficient. The application when filed generically disclosed administering to fibroblast cells a lentivirus encoding a connexin, whereby

the connexin is expressed in the cells and improves the electrical conductivity of the cells. Please therefore withdraw this rejection with respect to claims 86 and 94.

The rejection of claims 86 and 94 under 35 U.S.C. § 103(a)

Claims 86 and 94 stand rejected as obvious over Lee, U.S. 7,317,950 and general knowledge in the art as demonstrated by Teitz and Gruber patents. This rejection is respectfully traversed.

Lee is cited as teaching cardiac stimulation systems (claim 1) which comprise fibroblasts (claim 20) adapted to express connexin (claim 21).¹ The U.S. Patent and Trademark Office concedes that Lee does not teach administering a lentivirus encoding a connexin, but states that Lee teaches the use of integrating or episomal vectors. Col. 27, lines 55-60.

The office action notes that both Teitz and Gruber teach infection of fibroblasts with lentiviruses, evidencing the general state of the art.

Elements involved in making a *prima facie* case of obviousness are set forth in the MPEP, relying on Supreme Court jurisprudence:

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. **103**. 35 U.S.C. **132** requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability. ... The key to supporting any rejection under 35 U.S.C. **103** is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. **103** should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, 550 U.S. at ___, 82 USPQ2d at 1396.

MPEP § 2141.

¹ Note that claims 20 and 21 do not actually disclose a connection to the cardiac stimulation systems, as there is no antecedent basis for claim 19's conductive agent; claims 20 and 21 depend from claim 19.

The rejection does not put forth any detailed reasoning of why one of skill in the art would combine the teachings of Teitz and Gruber and Lee. Such detailed reasoning is required to make a *prima facie* case. Moreover, the office action provides a legal standard that relates to compositions (the invention is a method), and is not the proper legal standard in any event. The office action asserts without legal citation that to be non-obvious, a property of a composition must be one that skilled artisans “did not believe it would occur” or “it just would not be believed to occur.” These two phrases relate to something that is *incredible*. But incredible is not the standard for non-obviousness.

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to render obvious the claimed invention.

MPEP § 2142.

The U.S. Patent and Trademark Office has failed to make a *prima facie* case. Given that fact, applicants need not be put to the expense of proving that the results are unexpected.

Please withdraw the rejections and objections.

Respectfully submitted,
BANNER & WITCOFF, LTD.

By: / Sarah A. Kagan /
Sarah A. Kagan
Registration No. 32,141

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Customer No. 22907